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PTO/SB/21 (09-04)

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## TRANSMITTAL FORM

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Total Number of Pages in This Submission

7+

Application Number

10/630,074

Filing Date

07/30/2003

First Named Inventor

David R. Milich

Art Unit

1648

Examiner Name

Peng, B.

Attorney Docket Number

VACCINE-07971

### ENCLOSURES (Check all that apply)

<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input checked="" type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
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<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53		

Remarks

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Medlen & Carroll, LLP		
Signature	<i>Christine A. Lekutis</i>		
Printed name	Christine A. Lekutis		
Date	May 10, 2006	Reg. No.	51,934

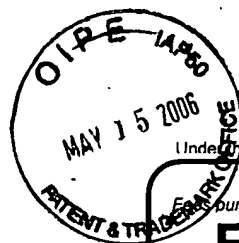
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Signature	<i>Cliff Cannon</i>		
Typed or printed name	Cliff Cannon-Cin	Date	May 10, 2006

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/17 (12-04v2)

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Effective on 12/08/2004.

Pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

# FEE TRANSMITTAL

## For FY 2005

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 180.00

**Complete if Known**

Application Number	10/630,074
Filing Date	07/30/2003
First Named Inventor	David R. Milich
Examiner Name	Peng, B.
Art Unit	1648
Attorney Docket No.	VACCINE-07971

**METHOD OF PAYMENT (check all that apply)**☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_☒ Deposit Account Deposit Account Number: 08-1290 Deposit Account Name: Medlen & Carroll, LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below☐ Charge fee(s) indicated below, except for the filing fee☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17☒ Credit any overpayments

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**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES****Fee Description**

Each claim over 20 (including Reissues)

Fee (\$)	Small Entity Fee (\$)
50	25

Each independent claim over 3 (including Reissues)

200	100
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Multiple dependent claims

360	180
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Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
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61	- 20 or HP = 0	x	=
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HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
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4	- 3 or HP = 0	x	=
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HP = highest number of independent claims paid for, if greater than 3.

**Multiple Dependent Claims**

Fee (\$)	Fee Paid (\$)
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**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
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- 100 =	/ 50 =	(round up to a whole number) x	=	
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**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

**Fees Paid (\$)**

Other (e.g., late filing surcharge): Information Disclosure Statement fee

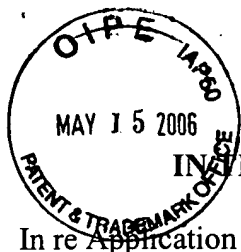
180

**SUBMITTED BY**

Signature		Registration No. (Attorney/Agent) 51,934	Telephone 415.904.6500
Name (Print/Type)	Christine A. Lekutis		Date May 10, 2006

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**PATENT**  
Attorney Docket No. **VACCINE-07971**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: **David R. Milich *et al.***

Serial No.: **10/630,074**

Group No.: **1648**

Filed: **07/30/2003**

Examiner: **Peng, B.**

Entitled: **Human Hepatitis B Virus Core Proteins As Vaccine Platforms  
And Methods Of Use Thereof**

**SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT**

**MS Amendment**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)**

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By: \_\_\_\_\_

Cliff Cannon-Cin

Dear Sir:

The citations listed below, copies of non-U.S. patents and published applications attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. § 1.56 and § 1.97. The Examiner is requested to make these citations of official record in this application:

- U.S. Patent No. 5,990,085 to Ireland *et al.*, "Inhibin-HBc fusion protein," (1999);
- U.S. Patent No. 6,887,464 to Coleman *et al.*, "Advanced antigen presentation platform," (2005);
- U.S. Publication No. US 2003/0099668 of Bachmann *et al.*, "Packaging of immunostimulatory substances into virus-like particles: method of preparation and use," (2003);
- U.S. Publication No. US 2004/0054139 of Page *et al.*, "Modification of hepatitis B core

05/16/2006 SSANDARA 00000018 10630074  
antigen," (2004);

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- U.S. Publication No. US 2004/0146524 of Lyons *et al.*, “Stabilized immunogenic HBc chimer particles,” (2004);
- U.S. Publication No. US 2004/0152876 of Birkett, “Immunogenic HBc chimer particles having enhanced stability,” (2004);
- U.S. Publication No. US 2004/0156864 of Birkett, “Immunogenic HBc chimer particles having enhanced stability,” (2004);
- U.S. Publication No. US 20040219164 of Coleman *et al.*, “Advanced antigen presentation platform,” (2004);
- U.S. Publication No. US 2005/0208068 of Milich *et al.*, “Malaria immunogen and vaccine,” (2005);
- Japanese Patent Application Publication No. JP7252300 of Okamoto “Antigen fused protein from duck hepatitis virus and human hepatitis virus and its production,” (1995) in Japanese with English translation of abstract and specification;
- PCT Publication No. WO 95/27083 of Milich *et al.*, “Method for diagnosing chronic hepatitis B virus infection,” (1995);
- PCT Publication No. WO 99/40934 of Birkett, “Strategically modified hepatitis B core proteins and their derivatives,” (1999);
- PCT Publication No. WO 00/46365 of Coleman *et al.*, “Advanced antigen presentation platform,” (2000);
- Belnap *et al.*, “Diversity of core antigen epitopes of hepatitis B virus,” *Proc Natl Acad Sci USA*, 100:10884-10889 (2003);
- Fietelson *et al.*, “Core particles of hepatitis B virus and ground squirrel hepatitis virus,” *J Virol*, 43:687-696 (1982);
- Fietelson *et al.*, “Monoclonal antibodies raised to purified woodchuck hepatitis virus core antigen particles demonstrate X antigen reactivity,” *Virology*, 177:357-366 (1990);
- Galibert *et al.*, “Nucleotide sequence of a cloned woodchuck hepatitis virus genome: Comparison with the hepatitis B virus sequence,” *J Virol*, 41:51-65 (1982);
- Gallina *et al.*, “A recombinant hepatitis B core antigen polypeptide with the protamine-like domain deleted self-assembles into capsid particles but fails to bind nucleic acids,” *J Virol*, 63:4645-4652 (1989);

- Kidd-Ljunggren *et al.*, "Genetic variability in hepatitis B viruses," J Gen Virol, 83:1267-1280 (2002);
- Koschel *et al.*, "Extensive mutagenesis of the hepatitis B virus core gene and mapping of mutations that allow capsid formation," J Virol, 73:2153-2160 (1999);
- Marion *et al.*, "A virus in Beechey ground squirrels that is related to hepatitis B virus of humans," Proc Natl Acad Sci USA, 77:241-2945 (1980);
- Mason *et al.*, "Virus of Pekin ducks with structural and biological relatedness to human hepatitis B virus," J Virol, 36:829-836 (1980);
- Milich *et al.*, "Immune response to hepatitis B virus core antigen (HBcAg): Localization of T cell recognition site within HBcAg/HBeAg," J Immunol, 139:1223-1231 (1987);
- Milich *et al.*, "Antibody production to the nucleocapsid and envelope of the hepatitis B virus primed by a single synthetic T cell site," Nature, 329:547-549 (1987);
- Milich *et al.*, "Comparative immunogenicity of hepatitis B virus core and E antigens" J Immunol, 141:3617-3624 (1988);
- Millman *et al.*, "Immunological Cross-reactivities of woodchuck and hepatitis B viral antigens," Infect Immun, 35:752-757 (1982);
- Ponzetto *et al.*, "Core antigen and antibody in woodchucks after infection with woodchuck hepatitis virus," J Virol, 52:70-76 (1984);
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- Pumpens and Grens, "Hepatitis B core particles as a universal display model: A structure-function basis for development," FEBS Letters, 442:1-6 (1999);
- Schodel *et al.*, "Immunization with recombinant woodchuck hepatitis virus nucleocapsid antigen or hepatitis B virus nucleocapsid antigen protects woodchucks from woodchuck hepatitis virus infection," Vaccine, 11:624-628 (1993);
- Shanmuganathan *et al.*, "Mapping of the cellular immune responses to woodchuck hepatitis core antigen epitopes in chronically infected woodchucks," J Med Virol, 52:128-135 (1997);

- Stannard *et al.*, "Antigenic cross-reactions between woodchuck hepatitis virus and human hepatitis B virus shown by immune electron microscopy," J Gen Virol, 64:975-980 (1983);
- Tarar *et al.*, "Expression of a human cytomegalovirus gp58 antigenic domain fused to the hepatitis B virus nucleocapsid protein," FEMS Immunol Med Microbiol, 16:183-192 (1996);
- Ulrich *et al.*, "Core particles of hepatitis B virus as carrier for foreign epitopes," Advances in Virus Research, 50:141-182 (1998);
- Werner *et al.*, "Serological relationship of woodchuck hepatitis virus to human hepatitis B virus," J Virol, 32:314-322 (1979);
- Zheng *et al.*, "The structure of hepadnaviral core antigens," J Biol Chem, 267:9422-9429 (1992); and
- Zlotnick *et al.*, "Localization of the C terminus of the assembly domain of hepatitis B virus capsid protein: Implications for morphogenesis and organization of encapsidated RNA," Proc Natl Acad Sci USA, 94:9556-9561 (1997).

This Information Disclosure Statement under 37 C.F.R. § 1.56 and § 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: May 10, 2006



Christine A. Lekutis  
Registration No. 51,934

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415/904-6500

FORM PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney Docket No.: VACCINE-07971	Serial No.: 10/630,074
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use Several Sheets If Necessary)				Applicant: David R. Milich <i>et al.</i>	
(37 CFR § 1.98(b))				Filing or 371(c) Date: 07/30/2003	Group Art Unit: 1648

U.S. PATENT DOCUMENTS							
Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	1	5,990,085	11/23/1999	Ireland <i>et al.</i>			
	2	6,887,464	05/03/2005	Coleman <i>et al.</i>			
	3	2003/0099668	05/29/2003	Bachmann <i>et al.</i>			
	4	2004/0054139	03/18/2004	Page <i>et al.</i>			
	5	2004/0146524	07/29/2004	Lyons <i>et al.</i>			
	6	2004/0152876	08/05/2004	Birkett			
	7	2004/0156864	08/12/2004	Birkett			
	8	2004/0219164	11/04/2004	Coleman <i>et al.</i>			

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS								
		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
							Yes	No
	9	JP7252300	10/03/1995	Japan			X	
	10	WO 95/27083	10/12/1995	WIPO				
	11	WO 99/40934	08/19/1999	WIPO				
	12	WO 00/46365	08/10/2000	WIPO				

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)		
	13	Belnap <i>et al.</i> , "Diversity of core antigen epitopes of hepatitis B virus," Proc Natl Acad Sci USA, 100:10884-10889 (2003)
	14	Fietelson <i>et al.</i> , "Core particles of hepatitis B virus and ground squirrel hepatitis virus," J Virol, 43:687-696 (1982)
	15	Fietelson <i>et al.</i> , "Monoclonal antibodies raised to purified woodchuck hepatitis virus core antigen particles demonstrate X antigen reactivity," Virology, 177:357-366 (1990)
	16	Galibert <i>et al.</i> , "Nucleotide sequence of a cloned woodchuck hepatitis virus genome: Comparison with the hepatitis B virus sequence," J Virol, 41:51-65 (1982)
	17	Gallina <i>et al.</i> , "A recombinant hepatitis B core antigen polypeptide with the protamine-like domain deleted self-assembles into capsid particles but fails to bind nucleic acids," J Virol, 63:4645-4652 (1989)
	18	Kidd-Ljunggren <i>et al.</i> , "Genetic variability in hepatitis B viruses," J Gen Virol, 83:1267-1280 (2002)
	19	Koschel <i>et al.</i> , "Extensive mutagenesis of the hepatitis B virus core gene and mapping of mutations that allow capsid formation," J Virol, 73:2153-2160 (1999)
	20	Marion <i>et al.</i> , "A virus in Beechey ground squirrels that is related to hepatitis B virus of humans," Proc Natl Acad Sci USA, 77:241-2945 (1980)
	21	Mason <i>et al.</i> , "Virus of Pekin ducks with structural and biological relatedness to human hepatitis B virus," J Virol, 36:829-836 (1980)
	22	Milich <i>et al.</i> , "Immune response to hepatitis B virus core antigen (HBcAg): Localization of T cell recognition site within HBcAg/HBeAg," J Immunol, 139:1223-1231 (1987)
	23	Milich <i>et al.</i> , "Antibody production to the nucleocapsid and envelope of the hepatitis B virus primed by a single synthetic T cell site," Nature, 329:547-549 (1987)
	24	Milich <i>et al.</i> , "Comparative immunogenicity of hepatitis B virus core and E antigens" J Immunol, 141:3617-3624 (1988)
	25	Millman <i>et al.</i> , "Immunological Cross-reactivities of woodchuck and hepatitis B viral antigens," Infect Immun, 35:752-757 (1982)

Examiner:	Date Considered:
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**EXAMINER:** Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

